



Appl. Serial No. 10/603,254  
Response dated March 29, 2006  
Response to Office Action dated December 29, 2005

# **I. Listing of Claims:**

This listing of claims is being provided for the Examiner's convenience. The claims are not being amended in this response.

## **Listing of Claims**

Claims 1-75. (cancelled)

Claim 76. (previously presented) A controlled release oral solid dosage form comprising a therapeutically effective amount of lovastatin and a controlled release carrier, said dosage form increasing the bioavailability of lovastatin and not increasing the bioavailability of lovastatin acid, as compared to the same amount of lovastatin administered in an immediate release dosage form, the dosage form providing a time to maximum plasma concentration (Tmax) at from about 10 to about 32 hours and a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 77. (previously presented) A controlled release oral solid dosage form of claim 76, wherein the bioavailability of lovastatin and its latent and active metabolites at steady state conditions is about 1.4 to about 2 fold the bioavailability attained by the same amount of lovastatin administered once daily in an immediate release dosage form, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 78. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form providing an AUC0-24h of lovastatin of greater than 100% of the AUC0-24h provided by the same amount of lovastatin administered in an immediate release dosage form, and said dosage form providing an AUC0-24h of lovastatin acid of less than 100% provided by the same amount of lovastatin administered in an immediate

release dosage form, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 79. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after administration of a single dose providing a ratio of AUC<sub>0-24h</sub> of lovastatin to AUC<sub>0-24h</sub> of lovastatin acid of from about 1:1 to about 3.6:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 80. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after once daily administration for 28 days providing a ratio of AUC<sub>0-24h</sub> of lovastatin to AUC<sub>0-24h</sub> of lovastatin acid of from about 0.74:1 to about 2:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 81. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after administration of a single dose providing a ratio of C<sub>max</sub> of lovastatin to C<sub>max</sub> of lovastatin acid of from about 1.1:1 to about 5:1.

Claim 82. (previously presented) A controlled release oral solid dosage form of claim 76, said dosage form after once daily administration for 28 days providing a ratio of C<sub>max</sub> of lovastatin to C<sub>max</sub> of lovastatin acid of from about 0.75:1 to about 3:1, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

Claim 83. (previously presented) The controlled release oral solid dosage form of claim 79, wherein the ratio is about 1.3:1.

Claim 84. (previously presented) The controlled release oral solid dosage form of claim 80, wherein the ratio is about 0.87:1.

Claims 85-87. (cancelled)

Claim 88. (previously presented) The controlled release oral solid dosage form of claim 76, wherein said controlled release carrier is incorporated into a matrix along with the lovastatin.

Claim 89. (previously presented) The controlled release oral solid dosage form of claim 76, wherein said controlled release carrier is applied as a controlled release coating to the lovastatin.